



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,434	03/15/2001	Glenn McGall	2719.2017-001	6484

22886 7590 07/03/2002

AFFYMETRIX, INC
ATTN: CHIEF IP COUNSEL, LEGAL DEPT.
3380 CENTRAL EXPRESSWAY
SANTA CLARA, CA 95051

EXAMINER

EPPS, JANET L

ART UNIT	PAPER NUMBER
----------	--------------

1635

DATE MAILED: 07/03/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,434

Applicant(s)

MCGALL ET AL.

Examiner

Janet L. Epps

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

2. Claims 1-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Earhart et al. in view of McGall et al., for the reasons of record set forth in the Official Action mailed 12-17-2001.

Applicant's arguments filed 4-09-2002 have been fully considered but they are not persuasive. Applicants traverse the instant rejection on the grounds that Earhart et al. in view of McGall et al. teach or suggest varying of iodine concentration and specifically do not recite wherein the concentration iodine used in the oxidation step ranges from about .005 M to about 0.05 M, wherein the iodine concentration is about .02 M. Moreover, Applicants argue that the claimed invention is not a matter of routine experimentation as asserted by the Examiner because particular parameter must first be recognized as a result-effective variable before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.

However, contrary to Applicant's assertions, the Earhart et al. reference clearly provides a method for specifically and uniformly synthesizing desired oligonucleotides within the elements (also called cells, or features) of a molecular array, wherein a phosphite triester group is oxidized by the addition of *iodine* in THF, pyridine, and water to form a phosphotriester group. (col. 7, lines 1-4). The instant invention requires the presence of iodine for the oxidation of a phosphite ester to a phosphate linkage, precisely the same result produced by the use of iodine in

Art Unit: 1635

the teachings of Earhart et al. The presence of iodine in this oxidation reaction, as taught by Earhart et al., is the variable in the reaction that results in the oxidation process. Applicant's claimed concentration of iodine for use in oxidation, ranging from about 0.02M, or 0.005M to .05 M are a matter of optimization since the prior art discloses the general conditions for the oxidation of a phosphite ester linkage to a phosphate linkage. Applicant's have not provided any evidence of unexpected results, and as stated in the prior action, "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See MPEP § 2144.05(II). In the instant case the general conditions of oxidation, namely wherein the oxidation occurs in the presence of a solution comprising iodine in THF, pyridine, and water, are disclosed in the prior art. Therefore Applicant's recitation of a particular range of iodine concentration used in an oxidation solution is not considered inventive since there is no evidence that the particular concentration range recited in the instant claims is critical to the claimed method.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Art Unit: 1635

Claim 5 has been amended to replace the term "P," representing a phosphoramidite group with the term "PR." Applicant's specification does not provide proper antecedent basis for this new limitation in this claim. Moreover, by amending the instant claim to recite "PR" it appears that this phosphoramidite group further comprises an "R" group as defined in the claim. Applicants reference page 5 and 21 in the specification as support for this amendment. However, these references are not sufficient to support the breadth of the claimed invention, since the claims are to be given the broadest reasonable interpretation in light of the specification. According to the definitions given in the specification as filed the term PR refers to a "phosphoramidite group" linked to an "R" group selected from hydrogen, hydroxy, protected hydroxy, halogen, and alkoxy. However, the specification as filed does not provide support for nucleotides modified at the 3'-O position with both a phosphoramidite and an R group. Applicants must cancel the new matter in response to this Office Action.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1635


however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-746-5143 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janet L Epps
Examiner
Art Unit 1635
June 25, 2002


SEAN MCGARRY
PRIMARY EXAMINER
1635